

METHODS OF PROTEIN PURIFICATION AND RECOVERY

ABSTRACT OF THE DISCLOSURE

5

Improved methods for purification and recovery of interferon-beta (IFN- β) and compositions comprising substantially monomeric IFN- β are provided. In one purification method, substantially purified IFN- β or variant thereof is precipitated and then dissolved in a guanidine hydrochloride (HCl) solution. Renaturation of the protein occurs by dilution with a suitable buffer. A similar purification method absent the precipitation step is also provided. Following renaturation of the IFN- β , residual guanidine HCl is removed by diafiltration or dialysis with a pharmaceutically acceptable buffer to prepare pharmaceutical compositions comprising substantially monomeric IFN- β .

15